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Submitter Information:

JUL 23 2007

This submission was prepared in May 2007 by:

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This submission was prepared for:

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Manufacturer/Sterilizer
150 Maimaigi-cho
Fujinomiya City, Shizuoka Pref.
Japan 418-0015
Registration #9681834

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Capiox® FX05 Hollow Fiber Oxygenator and Arterial Filter	Cardiopulmonary Bypass Oxygenator (Code: DTZ)	Oxygenator
	Cardiopulmonary Bypass Heat Exchanger (Code: DTR)	Heat Exchanger
	Cardiopulmonary Bypass Arterial Line Blood Filter (Code: DTM)	Arterial Filter
	Cardiopulmonary Bypass Blood Reservoir (Code DTN)	Blood Reservoir

Predicate Device:

The device submitted in this 510(k) maintains characteristics that are substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the following devices:

- Terumo's Capiox® RX05 Oxygenator/Reservoir – K022115.
- Terumo's Capiox® AF02X Arterial Filter – K011804.

Intended Use:

The Capiox FX05 device is intended to be used during open heart surgical procedures to transfer oxygen and remove carbon dioxide from blood and to control the blood temperature during cardiopulmonary bypass for periods up to 6 hours. The Capiox FX05 is a Neonate/Infant oxygenator intended for use in procedures up to a maximum flow of 1.5 L/min. The patient weight and BSA should be considered upon use.

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The FX05 Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedures.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

Principles of Operation and Technology:
The Capiox FX05 Oxygenator utilizes micro-porous membrane technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A polypropylene fiber bundle offers the porous membrane surface to sufficiently permit the movement of gases through the walls of the hollow fibers via diffusion. Diffusion occurs as oxygen moves from the gas-phase into the blood-phase; and carbon dioxide moves from the blood-phase into the gas-phase. The carbon dioxide is subsequently exhausted via a gas outlet port.

The Capiox FX05 device has an integrated heat exchanger that is comprised of a stainless steel bellows assembly encased in a polycarbonate housing. The stainless steel acts as a heat transfer material that permits heat that is generated from a temperature controlled external water bath to transverse across the walls of the stainless steel to effect the necessary temperature change upon circulating blood.

The Capiox FX device relies on external pump technology to allow for proper blood flow through the device. That is, after blood has been collected into a reservoir via gravity and/or vacuum assist, a pump (either roller or non-roller) will propel the blood into the oxygenator unit. The unit itself **is not** electro-mechanical in nature. Note: The external pump is responsible for facilitating blood flow through the extracorporeal circuit.

With respect to the filtration of arterial blood, the Capiox FX05 Oxygenator/Arterial Filter relies upon mechanical entrapment of particulates and emboli within the polyethylene terephthalate mesh as a means to remove those particulates from the blood. Air is removed from the blood stream via diffusion of the air into the gas phase of the oxygenator (i.e., inside of the polypropylene fibers) - where it is expelled through a gas outlet port located at the base of the oxygenator module.

Design and Materials:
With respect to the design of the oxygenator, the design of the Capiox FX05 device is a modification of the Capiox RX05 device that has an arterial filter integrated into the design. The design of the oxygenator device is such that it utilizes an integrated oxygenator/heat exchanger module that provides for gas transfer (blood oxygenation and carbon dioxide removal) and for blood temperature control. The RX Oxygenator/Arterial Filter device also utilizes a hardshell reservoir that is used to collect and store blood during a cardiopulmonary bypass procedure. Note: The Hardshell Reservoir has been previously cleared by FDA in K022115.

With respect to the design of the Arterial Filter, the filter contained within the oxygenator module is comprised of 32 micron PET (polyethylene terephalate) mesh material that is wrapped around the outer circumference of the oxygenator fiber bundle. This design permits the oxygenation of blood and removal of carbon dioxide as blood passes through the fiber bundle –

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and also facilitates blood filtration after the blood has been oxygenated. This filtration is designed to remove particulate matter and emboli prior to the blood's re-entry to the patient's body via mechanical entrapment. Air removal is accomplished by entrapment followed by permeation of the air into the hollow fibers of the oxygenator bundle – and subsequently is exhausted (along with carbon dioxide) via the gas outlet port.

The materials that are used in the construction of the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter includes, but are not limited to, polycarbonate, stainless steel, polyvinyl chloride, polyurethane, polyester, polypropylene, polyethylene terephthalate, polyethylene and X-Coating™.

Performance Evaluations:
Clinical studies involving patients are not necessary to demonstrate substantial equivalence of the subject device to the predicate devices. Substantial equivalence is demonstrated with the following *in-vitro* performance evaluations:

- Gas Transfer
- Effects on Blood Components (Hemolysis)
- Pressure Drop
- Mechanical Integrity
- Static Priming Volume
- Heat Exchanger Performance
- Filtration Efficiency
- Air Handling
- Tubing Connection Strength

Substantial Equivalence Comparison:
The information presented in this section depicts a comparison between the subject of this 510(k) submission, the Capiox FX05 Oxygenator/Arterial Filter, and the predicate Capiox RX05 Oxygenator and Capiox AF02X Arterial Filter devices.

- ***Comparison of Intended Use:***
  The Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter and the predicate Capiox RX05 devices are equivalent in their intended uses:

  Use during open heart surgical procedures to transfer oxygen and remove carbon dioxide from blood and to control the blood temperature during cardiopulmonary bypass procedures for periods up to 6 hours. Both the new and predicate devices are neonate/infant oxygenators intended for use in procedures requiring a maximum blood flow rate of 1.5 L/min. Both devices indicate that the patient weight and BSA should be considered upon use.

  The Hardshell Reservoir that is used with both the FX05 device and the predicate RX05 device may be used in vacuum assisted venous drainage procedures.

  The Capiox FX05 Oxygenator/Arterial Filter and the predicate Capiox AF02X Arterial Filter have the same intended uses. Both filters are intended to filter non-

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biologic particles and emboli and to facilitate air bubble removal from the blood flowing through a cardiotomy bypass circuit.

- ***Duration of Use:***
  The Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter and the predicate devices can be used in procedures lasting up to 6 hours.

- ***Comparison of Labeling***:
  Both the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter and the predicate Capiox devices are offered with adequate Instructions for Use and other product labeling as required by regulation. The Instructions for Use for the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter are presented in the Appendices of this submission; the Instructions for Use for the predicate Capiox devices are also presented in the Appendices of this submission.

- ***Comparison of Principles of Operation & Technology:***
  Both the Capiox FX05 Hollow Fiber Oxygenator and the predicate Capiox RX05 Oxygenator utilize the exact same technologies and principles of operation:

  Each device utilizes micro-porous membrane technology to facilitate the transfer of gases between a blood-phase environment and a gas-phase environment for the intent of satisfying the gas exchange needs of a patient during cardiopulmonary bypass surgery. A polypropylene fiber bundle provides a porous membrane surface to sufficiently allow the movement of gases through the walls of the hollow fibers via diffusion. Diffusion occurs as oxygen moves from the gas-phase into the blood-phase; and carbon dioxide moves from the blood-phase into the gas-phase. The carbon dioxide is subsequently exhausted via a gas outlet port.

  The Capiox FX05 device and the predicate Capiox RX05 device each have integrated heat exchangers that are comprised of a stainless steel bellows assembly. The stainless steel acts to provide a mechanism for the transfer of heat (generated from a temperature controlled external water bath) across the walls of the stainless steel to effect the necessary temperature change on the blood.

  The Capiox FX05 device and the predicate Capiox RX05 device each rely on external pump technology to allow for proper operation. That is, after blood has been collected into a reservoir, a pump (either roller or non-roller) will propel the blood into the oxygenator unit. The unit itself **is not** electro-mechanical in nature.

  With respect to the filtration of arterial blood, the Capiox FX05 Oxygenator/Arterial Filter and the predicate Capiox AF02X each rely upon mechanical entrapment of particulates and emboli. However, there are differences in their respective mechanisms for air removal:

  > The predicate Capiox AF02X removes air from the extracorporeal circuit by forcing the bubbles to move towards an air purge that is located in the upper region of the filter. With such a design, as air migrates to the purge port, it is easily removed via the port. By contrast, the Capiox FX05 arterial filter removes air by permeation of air into the gas phase (i.e., inside of the polypropylene fibers) of the oxygenator where it is expelled

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through a gas outlet port located at the base of the oxygenator module. This difference in operation does not present any additional issues of safety and/or effectiveness – but merely represent a difference in the manner in which air is removed from the patient's blood.

The Capiox FX05 Hollow Fiber Oxygenator/ and the predicate device are *substantially equivalent* in operation and technology. The noted differences do not raise any new issues of safety and effectiveness.

- ***Comparison of Design:***
  With respect to the design of the oxygenator, the design of the Capiox FX05 Hollow Fiber Oxygenator has the exact same design as the predicate device. In fact, the Capiox FX05 device is a modification of the Capiox RX05 device that has an arterial filter integrated into the design. The design of the oxygenator devices is exact in that they each utilize the same integrated oxygenator/heat exchanger module that provides for gas transfer (blood oxygenation and carbon dioxide removal) and for blood temperature control. Each of the devices also utilizes a hardshell reservoir that is used to collect and store blood during a cardiopulmonary bypass procedure. The reservoirs each provide for filtration of venous and cardiotomy blood as it enters the reservoir.

  Noted difference in design between the Capiox FX05 device and the predicate Capiox RX05 devices:

  The Capiox FX05 device has an integrated Arterial Filter that is enclosed within the oxygenator module of the device. In essence, the oxygenator and the integrated arterial filter are combined into a singular unit; whereas the Capiox RX05 device does not have an integrated Arterial Filter.

  With respect to the design of the Arterial Filter, the filter contained within the oxygenator module is comprised of a 32 micron PET (polyethylene terephalate) mesh material that is wrapped around the outer circumference of the oxygenator bundle. This design permits the oxygenation of blood and removal of carbon dioxide as blood passes through the fiber bundle – and also facilitates blood filtration after the blood has been oxygenated. This filtration is designed to remove particulate matter and emboli prior to the blood's re-entry to the patient's body via mechanical entrapment. Air removal is accomplished by entrapment followed by permeation of the air into the hollow fibers of the oxygenator bundle – and subsequently is exhausted (along with carbon dioxide) via the gas outlet port.
  By contrast, the predicate Capiox AF02X filter is a unit that is not integrated into an oxygenator, but rather, is a separate device that may be included in the extracorporeal circuit. When included in an extracorporeal circuit, the predicate Capiox AF02X is positioned between the oxygenator and the patient – thereby effecting the same surgical benefits as the Capiox FX device that is the subject of this premarket notification application.

  Terumo considers the design of the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter to be comparable and *substantially equivalent* to that of the predicate Capiox RX05 Oxygenator and Capiox Arterial Filter devices. The noted differences do not raise new issues of safety and effectiveness.

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- ***Comparison of Materials:***
  The Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter and the predicate Capiox devices are manufactured from the exact same materials. The devices (both new and predicate) are comprised of polycarbonate, stainless steel (heat exchanger), polypropylene (gas transfer material), polyvinyl chloride, polyurethane (adhesives), polyethylene, polyester and other materials that are typically used in the manufacture of medical devices.

  The Capiox FX05 devices and predicate devices contain polymethoxyethyl acrylate (PMEA), which is a biocompatible coating applied to the blood contacting surfaces of the devices. The PMEA coating is effective in reducing platelet adhesion to the device as blood circulates through the device during surgical procedures.

  The safety and efficacy of PMEA is well recognized and is used on several other medical devices that have been cleared by FDA.[1] The use of PMEA on medical devices has been demonstrated as safe for use on medical devices and it's use is well documented in the medical community.

  Terumo considers the Capiox FX05 device and the predicate devices to be comparable and *substantially equivalent* in materials of construction – especially since those materials are identical.

- ***Comparison of Performance:***
  The Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter exhibited performance that is deemed to be *substantially equivalent* to the performance of the predicate devices. This determination is based upon the results of the following tests:
  - Gas transfer testing.
  - Effects upon cellular blood components of the integral oxygenator/heat exchanger.
  - Pressure Drop Testing of the integral oxygenator/heat exchanger.
  - Mechanical Integrity of the integral oxygenator/heat exchanger.
  - Static Priming Volume of the integral oxygenator/heat exchanger.
  - Heat Exchanger performance evaluation (heat transfer).
  - Filtration Efficiency evaluations.
  - Air Handling testing.
  - Tubing Connection Strength

  Each of the above-indicated tests is reported in detail in Section 18 of this submission.

Conclusion:
In summary, Terumo deems the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter as substantially equivalent to the predicate Capiox RX05 Oxygenator and Capiox AF02X Arterial Filter device with respect to intended use, duration of use, design, materials, principles of

[1] Polymethoxyethyl acrylate is also used on X-Coated SX18/25 Oxygenators (K993772), Hardshell Reservoirs (K002238), CX*AF200X Arterial Filters (K002026), X-Coated Tubing (K003371), X-Coated Adapters (K003604), RX Hardshell Reservoirs (K013526), and X-Coated SX10 Oxygenators (K010443).

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operation, performance and specifications. It is further noted that any recognized differences do not raise any new issues of patient/user safety or product effectiveness.

Substantial Equivalence Statement:
The Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter and the predicate devices are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the subject device and the predicate devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}. Terumo further asserts that the ethylene oxide residues will not exceed the maximum residue limits at the time of product distribution.

- Terumo maintains biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:
In summary, the Capiox FX05 Hollow Fiber Oxygenator/Arterial Filter is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate oxygenator and reservoir devices identified in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2007

Terumo Corporation
c/o Mr. Gary A. Courtney, MBA, RAC
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K071572
Device Name: CAPIOX® FX05 Hollow Fiber Oxygenator with Integrated Arterial Filter
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: June 7, 2007
Received: June 8, 2007

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071572

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SECTION 4
Indications for Use

510(k) Number (if known): ~~Unknown at time of Submission~~ K071572

Device Name: **CAPIOX® FX05 Hollow Fiber Oxygenator with Integrated Arterial Filter**

Indications For Use:

The Capiox FX05 device is intended to be used during open heart surgical procedures to transfer oxygen and remove carbon dioxide from blood and to control the blood temperature during cardiopulmonary bypass for periods up to 6 hours. The Capiox FX05 is a Neonate/Infant oxygenator intended for use in procedures up to a maximum flow of 1.5 L/min. The patient weight and BSA should be considered upon use.

The FX05 Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedures.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071572